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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,198	04/04/2005	Yoko Matsuzawa	040894-7204	9611

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EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,198	MATSUZAWA ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response are acknowledged. Claim 14 remains the only claim pending and examined on the merits. Applicant maintains his arguments that amended claim 14, incorporating certain teachings of previous claims 1-13 into a single claim, is no longer taught by Applicant's earlier works. The Examiner has maintained the combination of previously added secondary reference (Tsilosani et al. (US 6,743,638), directed to the gaps which Applicant has cited (spherical in shape, containing pyranine), w/ Kogiso et al. (Primary Ref; with 2 Inventors common to this application).

Claim Rejections - 35 USC § 103

The rejection of claim 14 under 35 U.S.C. 102(b) as being anticipated by either Kogiso et al. (US 6,136,956, issued 10/24/00, two inventors in common with the present application) or Agency of Ind. Science & Techn. (now JP-B-3012932 Patent, 12/17/99, application JP 11-322787, cited in IDS of 4/4/05) - both discussed collectively under Kogiso et al. in view of Tsilosani et al. (US 6,743,638), is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive.

Applicant argues one of ordinary skill in the art would not have been motivated to arrive at, nor found predictable, the present invention based on the combination of Applicant's own earlier work (Kogiso et al.) in view of Tsilosani et al. Applicant relies upon:

> Liposome can be easily obtained by treating a suspension of a phospholipid. The production process thereof has been reported by Bangham *et al.* in the following reference
> documents:
>
> A.D.Bangham and R.M.C. Dawson, Nature (1958) 182, 1292-1293

A.D. Bangham, Nature (1961) 192, 1197-1198

A.D. Bangham and R.W. Home, Nature (1962) 196, 952-953.

However, none of these references or relevant passages thereof have been included in the response, such that the Examiner can fully consider these references as relevant to Applicant's arguments. Applicant goes on to indicate that Israelachavili et al. shows a 'correlation' between forms of packing molecules and the structures formed therefrom. The Examiner asserts this structure variables (e.g. truncated cone) based on various packing means, were known or predictable in the art at the time of the invention. But even if not, such a 'cone' structure is not claimed and this argument finds little application to the invention as claimed. Rather, the issue is whether this known compound (PRODUCT) could have been into a spherical microcapsule (PRODUCT) or any other PRODUCT, known at the time of the invention? The answer is yes. A product comprising a known product is still that product. Applicant's arguments are directed to methods of making products (e.g. truncated cone) via packing methodology – which bear no weight on the patentability of another product comprising a known product.

The rejection is repeated below for continuity of record:

The rejection is virtually identical, other than the recitation of Tsilosani et al.

It is noted that Applicant's earliest effective priority date is 10/7/02, greater than one year after the '956 patent issued.

Kogiso et al. teach:

1) the identical compound of formula I (entire document). As the present specification page 1-2 recites: "[i]t is described, for example, in Japanese Patent No. 3012932 and Chem. Comm., 1998, pp. 1791-1792 that the above compound forms a nano-scale fiber having a width of about 10 to 30 nm when an aqueous alkaline solution of the compound is gradually acidified"]. Kogiso et al. ;

2) linear products, namely fibers and fibrous assemblies, comprising the same; as well as spherical products, the easier to make product as discussed (col. 1, lines 21-34); and

3) a method of making the same using a substrate having hydrophilicity (e.g. glass vial), alkali metal salt, precipitated under a weakly acid atmosphere (Example 1 ; col. 2, lines 21-31; claims 5-7).

Specifically, the background on the art's processing of the easier made fine spherical versions of the '956 patented fibers/fibrous assemblies of Kogiso et al. is described in Kogiso et al. at col. 1, lines 21-34 and col. 3, lines 29-53:

"... well known, fibrous assemblies of a peptide lipid are widely employed in many applications, besides the applications as a drug delivery system or an adsorbent, in the fields of. medical and pharmaceutical sciences as a bioadaptable material, in the fields of electronic and information-processing technologies as a material of microelectronic parts, in the fields of food industries, agriculture, forestry and fiber industries as an emulsifying agent, stabilizer, dispersing agent or moisturizing agent and so on.

In the prior art, spherical assemblies obtained from a natural phospholipid or so-called liposomes are known among molecular aggregates formed from a phospholipid. Such a

spherical assembly is usually prepared by the thin-film method, thermal dispersion method, cholic acid method or reversed-layer evaporation method (see, for example, "Seitaimaku Jikkenhou" (Experimental Methods for Biomembra.nes), volume 2, page 185, published by Kyoritu Shuppan Co.).

Each of these prior art methods, however, requires extremely high skillfulness. In addition, the *molecular aggregates* obtained by these methods are limited to a *monolayered vesicle* or *spherical multilayered vesicle* and long fibrous assemblies cannot be prepared thereby. On the other hand, several method are disclosed, for example, in Journal of the American Chemical Society, volume 119, pages 9120-9124 (1997) for the preparation of a fibrous assembly from a synthetic amphiphilic compound in water. Each of these methods, however, is a method in which fibrous assemblies are obtained by spontaneous *precipitation* or crystallization from a hot concentrated *aqueous solution* containing an *amphiphilic compound* so that the yield of the product is necessarily limited.

[]

The various reagents, i.e. amino group-protective agent, carboxyl group-protective agent and coupling agent, and the procedures in the above described reaction can be conventional and freely selected from those used in the prior art for peptide synthesis. The intermediate peptide compounds formed in the course of the reaction can readily be isolated and purified by washing the reaction mixture with an acid or alkali aqueous solution followed by recrystallization or reprecipitation.

[]

The fine fibrous assembly of the invention is obtained from an aqueous solution of an alkali metal salt of the above described bola-form peptide lipid compound by causing precipitation thereof in a crystalline form.

The only thing Kogiso et al. does not expressly teach is that said fine spherical products have "uniform molecular orientation" or the word "microcapsule" (and that said microcapsule can encompass a substance having hydrophilicity, e.g. glass?). Hence the present rejection is made under 103, rather than 102, as expressly anticipated.

Tsilosani et al. teach nanoparticles/microcapsules/spherical liposomes of varying size, wherien "In the embodiment of FIG. 1, a particulate containment means such as a liposome (1) contains signal generating agents (2) which generate signal in

response to the presence of an ion such as H.sup.+. Suitable agents (2) are

therefore pyranine" (see Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have made a "uniformly oriented" and/or "microcapsule" spherical version, comprising pyranine as the visible agent therein, of the fiber/fibrous assemblies comprising compounds of Formula 1 in Kogiso et al., because Applicant's earlier work expressly states that making the spherical versions of such constructs is easier and known and the advantageous teachings of Tsilosani et al. indicate that spherical bodies of minute proportion comprising pyramine were known in this same art. And as previously stated, it was the linear, fiber versions that posed enablement & development issues, not spherical constructs, which were well known in the art to have uniform molecular orientation and be used in the biomedical fields as microcapsules, which

encapsulate water-attracted compounds/molecules. Thus, even though a secondary reference to the same need not have been necessary or further expounding necessary, as evident by the recited specification pages above, from Kogiso et al., such has not been provided to clarify the record.

Thus, from the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 9/15/2008

/Andrew D Kosar/
Primary Examiner, Art Unit 1654